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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,976	07/02/2003	Scott T. Broadley	BROADRE.023CP2	9018

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EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/16/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/16/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/613,976	Applicant(s) BROADLEY ET AL.	
	Examiner Kaj K. Olsen	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 and 53-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-43 is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-19 and 53-65 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11-3-03; 8-24-04; 12-3-04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I, claims 1-43 and 53-65 in the response of 1-29-2007 is acknowledged.

Information Disclosure Statement

2. In applicant's IDS filed on 11-03-2003, the reference to patent 3,962,765 was crossed off because the reference didn't correspond to the given name (Haddad) and had nothing to do with the technology of the instant invention. The reference to patent 4,592,824 to Gregory was also crossed off because the listed patent number did not have an inventor by this name and the number given was identical to the Smith reference listed right below it.
3. In applicant's IDS filed on 12-03-2004, the reference to patent 6,425,995 was crossed off because this patent has been withdrawn and is no longer available for viewing. All but one reference on the second page of the IDS has been crossed off because these references were already cited on the earlier page of the IDS.

Specification

4. The disclosure is objected to because of the following informalities: In paragraph 0001, the four blank spaces should be filled with "599,409", "7/29", "616,821" and "9/09" respectively. In addition, application 10/361,708 has matured into patent 7,025,871 and the paragraph should be amended to reflect that as well.

Appropriate correction is required.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-12 and 15-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,616,821 (hereafter "patent '821") in view of any of Nipkow et al (USP 5,470,453) or Jerrold-Jones (USP 3,793,176).

7. Claim 1 of the patent '821 set forth all the limitations of claim 1 of the instant invention, but the claim did not specify the presence of a filter member. Nipkow teaches the placement of porous elements (18, 20, 22) between the electrode element 14 and the reference junction 6 so as to assist in the prevention of undesirable ion movement. See the figure and col. 3, ll. 40-56. Jerrold-Jones also teaches the use of a porous element 48 between the electrode element 36 and the junction 18 to hold the Ag/AgCl packing material in place. See fig. 2 and 6 and col. 3, l. 63

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through col. 4, l. 2. These porous elements of Nipkow and Jerrold-Jones would read on the defined "filter member" giving the claim language their broadest reasonable interpretation.

Moreover, because these filtering members are porous, they would allow flow of any electrolyte solution through the filter member and the junction member and would thereby meet the claim language that they be "adapted to allow flow of the electrolyte". It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize a filtering members of either Nipkow or Jerrold-Jones for the reference electrode of patent '821 so as to either prevent metal ions from diffusing into the reference electrolyte or to hold the reference elements in a packed configuration so as to prevent their free diffusion into the reference solution.

8. With respect to the size of the pores present on the filtering member, the porous cotton of Nipkow and Jerrold-Jones would clearly exceed the nanometer sizes pores of the patent '821.

9. With respect to the pores being substantially straight and parallel, patent '821 already set forth that a porous fluid junction can be constructed with a substrate having pores that are substantially straight and parallel to one another. See claim 6. One possessing ordinary skill in the art would recognize that similarly constructed porous structures could be utilized for the porous materials of Nipkow and Jerrold-Jones.

10. Claims 1-12 and 14-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,599,409 (hereafter "patent '409") in view of any of Nipkow et al (USP 5,470,453) or Jerrold-Jones (USP 3,793,176).

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11. Claim 1 of patent '409 sets forth all the limitations of claim 1 of the instant invention, but did not explicitly recite the use of fewer than 100,000 nanochannels nor the use of a filtering membrane. With respect to the number of nanochannels, claim 5 of the patent '409 set forth that the number of nanochannels should be less than 10^5 . With respect to the filtering members, the teachings of Nipkow and Jerrold-Jones set forth these limitations as discussed above. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize a filtering members of either Nipkow or Jerrold-Jones for the reference electrode of patent '409 so as to either prevent metal ions from diffusing into the reference electrolyte or to hold the reference elements in a packed configuration so as to prevent their free diffusion into the reference solution.

12. Although claim 1 of the patent also sets forth a particular linear velocity and that the sample solution not substantially enter the array of nanochannels, claim 1 of the patent in view of Nipkow and Jerrold-Jones fully encompasses these limitations from the patent '409.

13. With respect to claim 14, see claim 11 of patent '409.

14. With respect to the various other dependent claims, see the discussion above.

15. Claims 53-59, 62, and 63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 8, and 9 of patent '821 or claims 1, 3-5 and 9 of patent '409 in view of Haynes et al (USP 4,886,505).

16. Claim 1 of patent '821 or claims 1 and 5 of patent '409 set forth all the limitations of claim 53, but did not explicitly recite the use of a coating of growth inhibitor on the junction member. Haynes teaches placing an antimicrobial coating onto the surfaces of devices that come in contact with biological fluids. See the abstract. Because the junction of patents '821 and '409

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comes in contact with samples fluids during use, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to apply an antimicrobial coating on the surfaces of the reference electrode in contact with the sample fluid so that the reference electrode does not get contaminated by earlier samples.

17. With respect to the use of copper, Haynes already recognized the use of copper as a growth inhibitor. See col. 2, ll. 26-30.

18. Claims 60 and 61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over patents '821 and '409 in view of Haynes as applied to claim 53 above and in view of Sarangapani (USP 6,165,366).

19. The patent claims and Haynes set forth all the limitation of the claims, but did not explicitly recite the use of a coating of biocide. Sarangapani discloses that other materials are usable as antimicrobial coatings, including biocides such as butyl paraben. See col. 3, ll. 30-37. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Sarangapani for the apparatus of patents '821 and '409 in view of Haynes, because the substitution of one known antimicrobial coating for another requires only routine skill in the art.

20. Claims 64 and 65 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over patents '821 and '409 in view of Haynes as applied to claim 53 above and in view of Roth et al (USP 4,708,776).

21. The patent claims and Haynes set forth all the limitations of the claims, but did not explicitly recite the use of a growth inhibitor in the electrolyte solution. Roth teaches that the addition of biocide to the reference electrolyte layer of a sensor presumably to prevent growth

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within the electrolyte layer. See the table in col. 6. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Roth for the apparatus of patents '821 or '409 in view of Haynes to prevent undesirable microbial growth within the electrolyte.

Allowable Subject Matter

22. Claims 20-43 are allowed.

23. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

24. The following is a statement of reasons for the indication of allowable subject matter: With respect to claim 13, the prior art does not disclose nor render obvious all the limitations of claim 10 and further comprising the filtering member having nanochannels. With respect to claims 20-27, the prior art does not disclose all the cumulative limitations of claim 20 with particular attention to the combination of junction member and filtering member where the filtering member is configured such that the electrolyte solution flows through the filter member and into the junction member. Because the filter member of Nipkow and Jerrold-Jones are located at a sealed chamber about the electrode element, there would be no flow through the actual filter element and the examiner is construing the claim language "wherein the filter member is configured such that the electrolyte solution flows through the filter member and into the junction member" to mean that the filter member must be positioned such that flow would proceed through both the filter member and the junction member. This is in contrast to claim 1,

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which merely required that the filter member be “adapted to allow flow”. Any filter member is inherently adapted to allow flow even if it isn’t configured to have the electrolyte flow through the filter member. With respect to claims 28-30, the prior art does not disclose nor render obvious all the cumulative limitations of claim 28 with particular attention to where the filter member and junction member are configured to allow a pressurized flow of electrolyte solution to flow through the pores of the filtering member and the nanochannels. Again, the filter member of Nipkow and Jerrold-Jones wouldn’t be configured to permit the flow of pressurized electrolyte solution through the pores of the filter member because the filter member is connected to a sealed environment. With respect to claims 31-43, the prior art does not disclose nor render obvious all the cumulative limitations of claim 31 with particular attention to the presence of first and second array of nanochannels configured in the defined manner.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Friday from 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 11, 2007



KAJ K. OLSEN
PRIMARY EXAMINER